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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,745	02/20/2002	Takayuki Koda	219843US0	3447
22850	7590	06/14/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 06/14/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/077,745

Applicant(s)

KODA ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 28-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-32 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/31/2006 has been entered.

New rejections and new grounds of rejection under 35 U.S.C. 112, first paragraph, are presented in the instant Office Action.

2. Claims 28-33 are pending and under consideration in this Office Action.

3. The rejection of claims 28, 29, 31, and 32 under 35 U.S.C. 102(b) as anticipated by Moriya et al. (EP 0955368) has been withdrawn in view of applicants amendment to the claims filed on 02/17/2006.

4. The rejection of claim 30 under 35 U.S.C. 103(a) as obvious over Moriya et al. (EP 0955368) in view of Ter-Sarkesyan et al. (SU 1637335), Erceg et al. (Aust J Biotechnol. 1990 Jul;4(3):177-82, 200), and Romaneko et al. (Mikrobiol Z. 2000 Jul-Aug;62(4): 29-37) has been withdrawn in view of applicants amendment to the claims filed on 02/17/2006..

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 28-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims that are directed toward any fertilizer comprising a genus of any and all derivatives of strain AJ13355 (FERM BP-6614) obtained by mutagenesis treatment or a recombinant DNA technique. The scope of the claims includes many bacterial strains with widely differing biological properties. Furthermore, the genus is highly variable because a significant number of differences between genus members exists.

The specification only discloses a single member of the claimed genus which is a deposited *Enterobacter agglomerans* AJ13355 strain of accession number of FERM BP-6614. The specification fails to provide a description of any additional species which are representative of the claimed genus. The specification fails to define those biological properties that are commonly possessed by members of the claimed genus that distinguish them from other bacterial strains. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the claimed genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of any fertilizer comprising a genus of any and all derivatives of strain AJ13355 (FERM BP-6614) obtained by mutagenesis treatment or a recombinant DNA technique.

8. Claims 28-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fertilizer comprising cells of the deposited *Enterobacter agglomerans* AJ13355 strain of accession number of FERM BP-6614; does not reasonably provide enablement for any fertilizer comprising any and all derivatives of strain AJ13355 (FERM BP-6614) obtained

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by mutagenesis treatment or a recombinant DNA technique. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any fertilizer comprising any and all derivatives of strain AJ13355 (FERM BP-6614) obtained by mutagenesis treatment or a recombinant DNA technique. The specification provides guidance, working examples, and a deposit of strain AJ13355 (FERM BP-6614). However, the specification does not provide guidance, prediction, and working examples for making any fertilizer comprising any and all derivatives of strain AJ13355 (FERM BP-6614) obtained by mutagenesis treatment or a recombinant DNA technique.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves making any and all derivatives of AJ13355 (FERM BP-6614) using any and all mutagens including UV light and mutagenic chemicals or using any recombinant DNA technique such as random PCR and random homologous recombination; and then searching and screening for any of these derivatives that can be used in a fertilizer. This trial and error experimentation is well outside the scope of routine experimentation. General teaching regarding screening and searching specific derivatives produced by any mutagenesis treatment or any recombinant DNA technique is not guidance for making the claimed invention.

In view of the above considerations applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims.

### ***Conclusion***

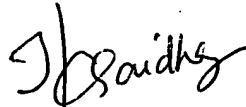
9. No claim is allowed.
10. Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

  
**TEKCHAND SAIDHA**  
**PRIMARY EXAMINER**